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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/106,264	12/13/2013	John Richard Nelson	264546-1	1767

6147 7590 04/17/2017

GENERAL ELECTRIC COMPANY
GLOBAL RESEARCH
ONE RESEARCH CIRCLE
BLDG. K1-3A59
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EXAMINER
OYEYEMI, OLAYINKA A

ART UNIT	PAPER NUMBER
1637	

NOTIFICATION DATE	DELIVERY MODE
04/17/2017	ELECTRONIC

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JOHN RICHARD NELSON, DAVID ROGER MOORE, BING LI, ROBERT SCOTT DUTHIE, and PATRICK McCOY SPOONER[1]

Appeal 2016-006182
Application 14/106,264
Technology Center 1600

Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and JOHN E. SCHNEIDER, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to amplification of double stranded DNA which have been rejected as being obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

STATEMENT OF THE CASE

"With the development of a variety of techniques for isolation, amplification and detection of nucleic acids, nucleic acid-based assays have

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[1] Appellant identifies the Real Party in Interest as General Electric Company. Br. 2.

emerged over the years as powerful tools for various applications such as diagnostic and forensic analysis." Spec. ¶3. The invention relates to amplification of a [double stranded] DNA (e.g., a genomic DNA) that is impregnated within a porous matrix using an endonuclease-assisted nucleic acid amplification and subsequent detection of amplicons within the porous matrix." Spec. ¶ 2.

Claims 1–24 are on appeal. Claim 1 is representative of the rejected claims and reads as follows:

> 1. A method of producing at least one amplicon based on a target double stranded DNA within a porous matrix comprising:
>
> (a) providing the porous matrix;
>
> (b) impregnating the target double stranded DNA within the porous matrix;
>
> (c) contacting the impregnated, target double stranded DNA with a DNA amplification reaction mixture comprising at least one inosine-containing primer, at least one 5'→ 3' exonuclease-deficient DNA polymerase having strand displacement activity, at least one nuclease that is capable of nicking a DNA at a residue 3' to an inosine residue, and a dNTP mixture;
>
> (d) amplifying at least one portion of the impregnated target double stranded DNA within the porous matrix using the DNA amplification reaction mixture of step (c) to produce the at least one amplicon within the porous matrix; and
>
> (e) determining a rate of production of the at least one amplicon within the porous matrix.

The claims stand rejected as follows:

Claims 1–5, 8, 11–18 and 20–24 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Nelson[2] in view of Cardy.[3]

Claims 6 and 7 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Nelson in view of Cardy and in further view of D'Costa[4], Ballantyne[5], Sasaki[6], and Hawkins.[7]

Claims 6 and 7 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Nelson in view of Cardy in further view of Ballantyne and Li.[8]

Claims 9 and 10 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Nelson in view of Cardy in further view of Beckers,[9]

Claim 19 has been rejected under 35 U.S.C. § 103(a) as unpatentable over Nelson in view of Cardy in further view of Duncan.[10]

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[2] Nelson et al., US 2009/0011472 A1, published Jan. 8, 2009 ("Nelson").
[3] Cardy et al., US 2006/0160078 A1, published July 20, 2006 ("Cardy").
[4] D'Costa et al., US 2009/0208975 A1, published Aug. 20, 2009 ("D'Costa").
[5] Ballantyne, et al., *Molecular crowding increases the amplification success of multiple displacement amplification and short tandem repeat genotyping,* 355 Anal. Biochem. 298 (2006) ("Ballantyne").
[6] Sasaki et al., *Effect of molecular crowding on DNA polymerase activity,* 1 Biotechnol. J. 445 (2006) ("Sasaki").
[7] Hawkins, US 5,898,071, issued Apr. 27, 1999 ("Hawkins").
[8] Li et al., US 2013/0171669 A1, published July, 4, 2013 ("Li").
[9] Beckers et al., WO 2010/066908 A1, published June 17, 2010 ("Beckers").
[10] Duncan et al., US 2010/0240102 A1, published Sept. 23, 2010 ("Duncan").

CLAIMS 1–5, 8, 11–18, and 20–24

Issue

Then issue is whether a preponderance of evidence supports the Examiner's finding that claims 1–5, 8, 11–18, and 20–24 would have been obvious over Nelson combined with Cardy.

The Examiner finds that Nelson teaches amplification of double stranded DNA with an amplification mixture comprising the same elements as recited in the instant claims. Final Act. 5. The Examiner also finds that Nelson teaches measuring the quantity of an amplicon or a rate of production of at least one amplicon. Final Act. 6. The Examiner finds that Nelson does not teach amplification in a porous matrix, Final Act. 8. The Examiner finds that Cardy teaches amplification of DNA in a porous matrix. *Id.* The Examiner concludes that

> [i]t would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method of Nelson et al. by providing a porous matrix as taught by Cardy et al. for the purpose of producing at least one amplicon from a target double stranded DNA that has been impregnated within a porous matrix such as taught by Cardy et al.

Final Act. 9.

Appellants contend that the references do not teach determining a rate or quantity of amplicon production in a porous matrix. Appeal Br. 7–8. Appellants also argue that the technique in Nelson cannot be used to modify Cardy as proposed by the Examiner. Appeal Br. 8–9. Appellants contend that the Examiner engaged in improper hindsight in combining the references. Appeal Br. 9–10.

Findings of Fact

We adopt as our own the Examiner's findings and analysis. The following findings are included for emphasis and reference convenience.

FF1. Nelson discloses a method for amplifying DNA. Nelson, Abstract.

FF2. Nelson discloses determining the quantity of amplification produced by the method. Nelson ¶ 173.

FF3. Cardy teaches a method for amplifying DNA in a porous matrix. Cardy ¶ 30.

FF4. Cardy teaches detecting "the presence and/or amount of a nucleic acid sequence of interest in the sample" within a detection zone. Cardy ¶ 28.

FF5. The Specification teaches that "[o]nce the target DNA amplification is over, the amplicons may be detected within the porous matrix to determine the presence, absence or quantity of a particular amplicon and/or to detect the reaction kinetics of DNA amplification." Spec. ¶ 35.

FF6. The Specification teaches that "[t]he amplicons produced by various embodiments of the present DNA amplification methods may be determined qualitatively or quantitatively by any of the existing techniques. The amplicons may be detected either within the porous matrix or outside of the porous matrix." Spec. ¶ 48.

Principles of Law

"[N]ot unlike a determination of infringement, a determination of anticipation, as well as obviousness, involves two steps. First is construing

the claim, . . . followed by, in the case of anticipation or obviousness, a comparison of the construed claim to the prior art." *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 714 (Fed. Cir. 1998).

"[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification." *In re Hyatt,* 211 F.3d 1367, 1372 (Fed. Cir. 2000).

"[W]hile it is true that claims are to be interpreted *in light of* the specification . . . , it does not follow that limitations from the specification may be read into the claims. . . . [T]he claims define the invention." *Sjolund v. Musland*, 847 F.2d 1573, 1581–82 (Fed. Cir. 1988).

"Absent an express definition in their specification, the fact that appellants can point to definitions or usages that conform to their interpretation does not make the PTO's definition unreasonable when the PTO can point to other sources that support its interpretation." *In re Morris*, 127 F.3d 1048, 1056 (Fed. Cir. 1997).

A proper § 103 analysis requires "a searching comparison of the claimed invention—including all its limitations—with the teaching of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995).

"Claims may be obvious in view of a combination of references, even if the features of one reference cannot be substituted physically into the structure of the other reference." *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1013 (Fed. Cir. 1983).

"Any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the

time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971).

Analysis

Appellants' principle arguments rely on the premise that step (e) of claim 1 requires that the determination step take place within the porous matrix. Appeal Br. 7–8, Reply Br. 2–3. Appellants point to the portion of the Specification that states that "the amplicons may be detected within the porous matrix" to determine the quantity of amplicon or the reaction rate to support their contention that step (e) requires that the determination be done within the porous matrix. Appeal Br. 8, Reply Br. 3.

The Examiner finds that the language of step (e) does not require that the determination step be performed in the porous matrix and that the determination step may be performed outside the porous matrix. Ans. 15–16.

We agree with the Examiner that step (e) does not require that the determining step must be performed within the porous matrix. During prosecution, claim terms are given their broadest reasonable interpretation. *In re Hyatt,* 211 F.3d at 1372. While the specification can be useful in interpreting the claims, it is improper to import limitations into the claims. *Sjolund*, 847 F.2d at 1581–82.

Step (e) of claim 1 reads "determining a rate of production of the at least one amplicon within the porous matrix." Appeal Br. 13 (App'x of Clams on Appeal). As presently written, it is unclear whether the term "within the porous matrix" applies to where the production rate of an

amplicon located in a porous matrix is determined or simply to the location of the amplicon. Given this ambiguity, we are compelled to agree with the Examiner that step (e) can be reasonably interpreted such that the determining step is performed outside the porous matrix. Ans. 15–16.

The teachings of the Specification support the Examiner's interpretation. As Appellants point out, the Specification teaches that the determining step *may* be performed within the porous matrix. Appeal Br. 8, FF5. The use of the word may indicates that determination of the production rate within the porous matrix is permissive and not a required step. Moreover, the Specification also teaches that the determining step may be performed either within or outside the porous matrix. FF6.

From the language of the Specification it is clear that when Appellants intended to limit the determining step to the porous matrix, they linked the concepts together. For example in paragraph 35 Appellants use the term "the amplicons may be detected within the porous matrix." Similarly in paragraph 48 it states that "[t]he amplicons may be detected either within the porous matrix or outside of the porous matrix." In both cases the detection step was clearly linked to the position either within or outside the matrix. It is clear that had Appellants intended to limit the determining step to the porous matrix, they would have written the claims in the same manner as the Specification.

Appellants also contend that the method of Nelson is not properly combinable with that of Cardy as Nelson discloses the use of serially diluted starting materials to produce amplification products in solution and that Cardy discloses a lateral flow process. Appeal Br. 8–9. Appellants contend

that one skilled in the art would not have looked to Nelson for a quantification technique. Appeal Br. 9. We are unpersuaded. As the Examiner points out, both Cardy and Nelson teach measuring the quantity of the amplicon produced. Ans. 16. We agree with the Examiner that

> the step of determining a rate of production of the at least one amplicon within the porous matrix is prima facie obvious since the ordinary skilled artisan wanting to quantitate the amount of amplification product produced by the method of Nelson, as a function of time (i.e. determine the instant rate of production of at least one amplicon) would have just measured the quantity of amplification product produced within the matrix by providing labeling reagent(s)/capture agent(s) disclosed by Nelson or Cardy to the porous matrix (during or following the amplification) and monitored the signals from such labeling reagents/ capture agents as a function of time.

Ans. 17.

We are also not persuaded by Appellants' argument that the Examiner engaged in impermissible hindsight. Appeal Br. 9–10. We find that the Examiner has relied solely on knowledge which was within the level of ordinary skill at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure. The Examiner has not resorted to improper use of hindsight.

We conclude that a preponderance of the evidence supports the Examiner's conclusion that claim 1 would have been obvious over Nelson and Cardy under 35 U.S.C. § 103(a). Claims 2–5[11], 8, 11–18, and 20–24

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[11] In their Reply Brief, Appellants raise for the first time a separate argument for the patentability of claim 3. Reply Br. 3. Arguments presented for the first time in a reply brief will not be considered. 37 C.F.R. § 41.41 (b)(2).

have not been argued separately and therefore fall with claim. 37 C.F.R. § 41.37(c)(1)(iv).

CLAIMS 6, 7, 10, and 19

While the patentability of claims 6, 7, 10, and 19 have been argued separately, the arguments do nothing more that refer to the arguments relating to Nelson and Cardy discussed. Appeal Br. 10–12. For the reasons stated above, we affirm the rejection of these claims.

SUMMARY

We affirm the rejections under 35 U.S.C. § 103(a).

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED